



Do's and Don'ts for a Successful Review



This talk provides general guidance on submitting a competitive application.

The guidance is based on years of peer review experience and contains information from NIAID program, grants management, and review officers.



Units for HIV/AIDS Clinical Trials Networks

■ RFA-AI-05-002

<http://grants2.nih.gov/grants/guide/rfa-files/RFA-AI-05-002.html>

■ Solicits U01 Cooperative Agreement Applications

- Applications will undergo NIH / NIAID Peer Review
- Approximately 75-100 awards anticipated



NIH / NIAID Peer Review

-  Competitive process
-  Managed by Scientific Review Administrator(s)
-  Follows NIH-NIAID policies / procedures



Factors that Determine Awards

- ✚ Scientific Merit of proposed Clinical Research Sites and the CTU
- ✚ Availability of funds
- ✚ Relevance to scientific programs identified in the RFA
- ✚ Adequate representation of populations impacted/threatened by HIV/AIDS



Elements of Successful Applications

- ✚ New, original ideas
- ✚ Focused research and administrative plans/approaches
- ✚ Appropriate resources/facilities
- ✚ Knowledge of relevant published work



Elements of Successful Applications

- ✚ Adequate staff with experience/training in essential methodology
- ✚ Appropriate, feasible contingency plans/future directions
- ✚ Applications written, developed, prepared appropriately according to NIH / NIAID requirements



Why Applications Do Not Succeed

- ✚ Superficial, unfocused research, organizational, administrative plan(s)
- ✚ Insufficient knowledge of relevant literature
- ✚ PI and/or key staff deficient in effort, number, experience, training



Why Applications Do Not Succeed

- ✚ Excessive work for requested period
- ✚ Insufficient details in the application
- ✚ Inadequate attention to the submission requirements of the NIH/NIAID



“The Rules” for Preparing Successful Grant Applications



Rule 1:

Your application must be
complete in itself.



*1. Your application must be complete in itself... SRA's
Instructions to Reviewers:*

Base priority scores **ONLY** on...

- ✚ What is in the application
 - ✚ 5 Basic review criteria and
 - ✚ RFA-specific review criteria
- (Applications are not compared)



1. Your application must be complete in itself...

5 Basic Review Criteria

Significance

Approach

Innovation

Investigator

Environment



1. Your application must be complete in itself...

Significance

- ❑ Rationale for the work
- ❑ Expected benefits/applications of work
- ❑ Relevance to important problem(s)
- ❑ Clear, focused aims / goals



1. Your application must be complete in itself...

Approach

- Methods - clear, specific, detailed
- Why the methods were chosen
- Preliminary data / past clinical research experience



1. Your application must be complete in itself...

Approach

- ❑ Possible problems and solutions
- ❑ Strategy for reaching goals on time
- ❑ Priority order of work
- ❑ Plans for analysis of results



1. Your application must be complete in itself...

Innovation

❏ What is new/innovative about research question(s) or method(s)?

(Access to populations; Recruitment/Retention; Scientific/clinical capabilities, etc.)



1. Your application must be complete in itself...

Investigators

- ✚ Specific responsibilities – PI / Key staff
- ✚ Training/experience qualified for role(s)
- ✚ Specific, relevant past accomplishments
- ✚ Consultants/collaborators for needed expertise
- ✚ Staff proposed at sufficient effort for project



1. Your application must be complete in itself...

Environment

- ✿ Organizational framework, how it contributes to success
- ✿ Coordination/communication plans among staff, organizations
- ✿ Special resources/facilities available /dedicated to the project



1: Your Application must be complete in itself...

RFA specific sections /evaluation criteria:

- ✚ Clinical Trials Unit (Administrative Component)
- ✚ Clinical Research Sites
- ✚ Units with Foreign Components
- ✚ Mentoring Partnership(s) (optional)
- ✚ Human Subjects Research
- ✚ Biohazards
- ✚ Inclusion of Women, Minorities and Children in Research
- ✚ Budget



1. Your application must be complete in itself...

Description (Abstract – page 2)

- ❑ Clear, factual synopsis of the application
- ❑ Specific PHS Form 398 requirements
- ❑ Description helps to orient reviewers
- ❑ Carefully write the Description
- ❑ Writing the Description last helps to make it comprehensive



Rule 2

Make it Easy for the Reviewers



2. Make it easy for the reviewers...

- ✿ NIAID specific guidance and forms:

http://www.niaid.nih.gov/daids/rfa/network06/ctu_rfa_instructions.htm

- ✿ Clear overall organization
- ✿ Concise, clear writing, sentence structure
- ✿ Visually appealing: Charts, Tables, Diagrams, Flow-charts, Proper font size, Correct page limits
- ✿ Use Appendices well
- ✿ Cross-reference, label, number everything
- ✿ Remember the Review Criteria when writing



Rule 3

Be Realistic.



3. Be realistic...

- ✚ Identify potential limitations, problems
- ✚ Indicate how you propose to deal with them
- ✚ Biosketches – only include relevant information
- ✚ Budget -Don't intentionally over- / under-estimate
- ✚ Do not indulge in self-promotion
- ✚ Do not assume reviewers will know what you mean.
- ✚ Do not assume reviewers will ignore review criteria



Rule 4

Read and Carefully
Follow Instructions.



4. Read and Carefully, Follow Instructions...

***PHS Research Grant Application Kit
(Form PHS 398 - Revised 9/2004)***

Basic forms / instructions for NIH grant applications

<http://grants.nih.gov/grants/funding/phs398/phs398.html>



4. Read and Carefully follow instructions...

❖ Special requirements for RFA AI-05-002

- ❑ RFA supercedes PHS 398 when they differ; otherwise use PHS 398
- ❑ http://www.niaid.nih.gov/daids/rfa/network06/ctu_rfa_instructions.htm
- ❑ http://www.niaid.nih.gov/daids/rfa/network06/units_required_forms.htm
- ❑ http://www.niaid.nih.gov/daids/rfa/network06/units_protocol_schema.htm

❖ Observe deadlines for application submission

❖ Submit the proper number of copies

❖ Send application materials to the correct ADDRESSES

Center for Scientific Review & the NIAID get documents



Rule 5

Don't Work in Isolation.



5. *Don't work in isolation...*

- ✦ Seek out collaborations; Network widely
- ✦ Use NIH/NIAID Resources on WWW
- ✦ If possible read successful application(s) & summary statement(s)
- ✦ Ask for honest feedback from senior investigators
- ✦ Allow time for their advice and your revision
- ✦ Fix problems before submitting the application



Rule 6

Be Aware of Changes
in Policy and Procedure



6. Be aware of changes in policy & procedure...

☛ Check NIAID / DAIDS Web Site :

<http://www.niaid.nih.gov/daids>

for information relevant to this solicitation



6. Be aware of changes in science and policies...

DAIDS Program Officers– Programmatic issues

NIAID Grants Management Officers – Fiscal/Budget

NAID Scientific Review Administrators – Submission/Review

NIAID <http://www.niaid.nih.gov/ncn/default.htm>

NIAID Partners

<http://www.niaid.nih.gov/daids/rfa/network06/partner.htm>

Center for Scientific Review <http://www.csr.nih.gov/>

Your institution / Your colleagues





Rule 7

Don't Give Up.



7. *Don't give up...*

- ✿ Not every application / applicant can win an award
- ✿ Learn, grow, succeed- many do
 - ▣ Study reviewer comments in the summary statement
 - ▣ Use comments to improve application(s)
 - ▣ Keep a positive attitude
 - ▣ Identify other funding initiatives
 - ▣ Revise and submit future application(s)



Questions?